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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,940	FIKE, RICHARD M.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15,16,18-29,31-34 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15,16,18-29,31-34 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed April 23, 2004.

Claims 1-10, 15, 16, 18-29, 31-34 and 36-44 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed December 23, 2004, that is not addressed in this action has been withdrawn.

Applicant's arguments with respect to the rejection of claims 1-10, 15, 16, 18-29, 31-34 and 36-44 under 35 USC § 102(b) (as being anticipated by Fike) have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

The information disclosure statements filed December 22, 2003 and January 29, 2004 have been considered, and a signed and initialed copy of the form PTO-1449s are attached to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 8, 10, 15, 16, 18, 19, 28, 29, 31-33, 36, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Altas, RM (The Handbook of Microbiological Media, 1997, CFC Press; see entire document; henceforth Atlas).

Atlas teaches a number of media preparations for culturing cells. In these media preparations, Atlas teaches that the preferred method of maintaining an appropriate pH is through the use of pH-opposing forms (i.e., monobasic versus dibasic) phosphate salts (see for example page 10, the paragraphs bridging the left and right columns). In a particular example of a medium formulation (A medium 5X), 52.5 g of K_2HPO_4 and 22.5 g of KH_2PO_4 are added to the other media components (see for example page 18-19); when these components are reconstituted in water, they result in an automatically pH-adjusting medium (it is noted that there is no additional pH-adjusting step) that is capable of sustaining the growth of bacterial cells such as *E. coli*. However, prior to reconstitution, they represent a dry powdered medium that produces a desired final pH upon reconstitution, and the recipe represents a method of making the dry medium. Similarly, because Atlas teaches that *E. coli* cells can be cultured using the reconstituted media, Atlas teaches a method of culturing bacterial cells with an automatically pH-adjusting culture medium, and also teaches a composition comprising the culture medium and a host cell. Finally, it is noted that the kits as claimed are defined by the components therein, and are anticipated by the teaching of the medium composition; importantly, the culture medium also comprises other culture medium supplements, such as ammonium sulfate ($NH_4(SO_4)_2$).

Claims 1, 2, 5, 6, 8, 10, 15, 16, 18, 19, 28, 29, 31-33, 36, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Fluka Cat. No. 86494 (Terrific Broth; see entire document; henceforth Fluka).

Fluka teaches a medium preparation that comprises pH-opposing forms of buffer salts, namely K_2HPO_4 and KH_2PO_4 (see for example the "Ingredients" section of Fluka). Prior to

reconstitution, the medium preparation represents a dry powdered medium that produces a desired final pH upon reconstitution, and the recipe represents a method of making the dry medium. Upon reconstitution of the powder, the medium gives a pH that is desired because the medium is conducive for the growth of bacterial cells, given the "Starter Culture" method disclosed under the "Directions" section of the disclosure. Thus, Fluka also teaches a method of reconstituting the dry powdered culture medium into a liquid culture, followed by a method of growing bacterial cells such as *E. coli* in the reconstituted culture medium (see for example the "Directions" section). Upon the incubation of the bacterial cells in the presence of the culture medium, Fluka teaches a composition comprising the culture medium and at least one bacterial cell. Since the kits as claimed are defined by the components therein, they are anticipated by the teaching of the medium composition; importantly, the culture medium also comprises other culture medium supplements, such as Yeast Extract and glycerol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 15, 16, 18-29, 31-34 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fike *et al.* (WO 98/36051, as IDS reference AO4; henceforth Fike; see entire document) in view of Atlas (as cited above).

Fike teaches a method for producing nutritive media comprising media supplements and buffers in a dry powder, followed by sterilization of the powder with gamma-rays and packaging of the powder (see for example page 6, lines 9-19). The media can be bacterial media, yeast media, plant culture media or animal cell culture media (see for example page 6, lines 21-23). Supplements for the media include powdered sera from animals, plants, etc., cytokines and growth factors, other proteins, vitamins, amino acids, co-factors, lipids, extracts of animal tissues or glands, and buffers (see for example page 6, line 25 to page 7, line 26). Upon reconstitution of the dry powder in a solvent of interest, the media automatically adjusts to a particular pH without the use of a pH-adjusting agent such as an acid or a base (see for example page 20, lines 3-26). Fike also teaches methods of using the media to culture cells (bacteria, yeast, animal, etc.), comprising reconstituting the media compositions of the above method in a solvent such as water or serum, and contacting cells with the solution under conditions that are favorable for growth of the cell (see for example page 8, lines 22-26). Particular cells that can be used in the method are animal/human cells, including normal, transformed diseased, etc. cells (see for example page 8, line 22 to page 9, line 5). Fike also teaches kits for use in the above process of culturing cells comprising packaging the media, and in some embodiments including the dried cells for culturing (see for example page 8, lines 6-11). Fike must have used sodium bicarbonate that does not liberate CO_2 because the invention as taught by Fike could not be practiced if carbon dioxide was liberated in the packaged media. Fike requires that the powdered media be sterilized by gamma irradiation. The accumulation of carbon dioxide in an enclosed package would result in a build up of pressure, eventually leading to an explosion of the container,

thereby comprising the sterility of the dry powder and counteracting a distinct step in the process as taught by Fike.

Fike does not specifically teach using pH-opposing forms of buffer salts to maintain the pH of the medium at a desired level. Rather, Fike teaches using a pH-adjusting agent such as HCl or NaOH in the dry powder to obtain a desired pH upon reconstitution of the dry powder. However, Fike clearly suggests that the media automatically adjust to a particular pH without the further use of an adjusting agent (see for example page 20, lines 3-26).

Atlas teaches a number of media preparations for culturing cells. In these media preparations, Atlas teaches that a common method of maintaining an appropriate pH is through the use of pH-opposing forms (i.e., monobasic versus dibasic) of phosphate salts (see for example page 10, the paragraphs bridging the left and right columns). This represents an alternative mechanism of obtaining a desired pH upon the reconstitution of a dry powdered medium, without the need for pH-adjusting agents such as HCl and NaOH. Buffers that would satisfy this requirement are well known in the art, and include buffer salts such as sodium phosphate (mono- and dibasic), potassium phosphate (mono- and dibasic), sodium bicarbonate (mono- and dibasic), etc.

It would have been obvious to combine the teachings of Atlas with those of Fike because each teaching concerns the preparation of medium that has a desired pH upon reconstitution. Furthermore, Atlas teaches a method of obtaining a desired pH without using extraneous pH-adjusting agents such as HCl or NaOH; this is in accordance with the suggestion in Fike that extraneous pH-adjusting agents be omitted from the media preparations. The ordinary skilled artisan would have been motivated to combine the teachings of Atlas and Fike because Atlas

teaches that the use of appropriate concentration of pH-opposing salts is a common manner of maintaining the pH of culture medium, while at the same time meeting the suggestion of Fike to not use additional pH-adjusting agents. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when practicing the claimed invention given the combined teachings of Atlas and Fike.

Claims 1-10, 15, 16, 18-29, 31-34 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fike *et al.* (WO 98/36051, as IDS reference AO4; henceforth Fike; see entire document) in view of Fluka (as cited above).

Fike teaches the same elements set forth above in the rejection of claims 1-10, 15, 16, 18-29, 31-34 and 36-44 by Fike in view of Atlas.

Fike does not specifically teach using pH-opposing forms of buffer salts to maintain the pH of the medium at a desired level. Rather, Fike teaches using a pH-adjusting agent such as HCl or NaOH in the dry powder to obtain a desired pH upon reconstitution of the dry powder. However, Fike clearly suggests that the media automatically adjust to a particular pH without the further use of an adjusting agent (see for example page 20, lines 3-26).

Fluka teaches a media preparation that comprises pH-opposing forms of buffer salts, wherein the pH-opposing forms of the medium are present to buffer the medium against a drop in pH (see for example the "Ingredients" and "Directions" sections of Fluka). This represents an alternative mechanism of obtaining a desired pH upon the reconstitution of a dry powdered medium, without the need for pH-adjusting agents such as HCl and NaOH. Fluka also teaches reconstituting the medium preparation containing a given cell, methods of culturing the cell in

the reconstituted medium, as well as kits and compositions thereof. Buffers that would satisfy this requirement are well known in the art, and include buffer salts such as sodium phosphate (mono- and dibasic), potassium phosphate (mono- and dibasic), sodium bicarbonate (mono- and dibasic), etc.

It would have been obvious to combine the teachings of Fluka with those of Fike because each teaching concerns the preparation of medium that has a desired pH upon reconstitution. Furthermore, Fluka teaches a method of obtaining a desired pH without using extraneous pH-adjusting agents such as HCl or NaOH; this is in accordance with the suggestion in Fike that extraneous pH-adjusting agents be omitted from the media preparations. The ordinary skilled artisan would have been motivated to combine the teachings of Fluka and Fike because Fluka teaches that the use of appropriate concentration of pH-opposing salts is a well-known and accepted manner of maintaining the pH of culture medium, while at the same time meeting the suggestion of Fike to not use additional pH-adjusting agents. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when practicing the claimed invention given the combined teachings of Fluka and Fike.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER